Description

BACKGROUND OF THE INVENTION

The transport and storage of blood products requires a consistent cool chain in the temperature ranges of 2 to 6°C, < -20°C and between 20° to 24°C in order to maintain its life giving properties. To satisfy these requirements, blood products are transported in temperature regulated containers which are either passively cooled by means of accumulators or by active electrical cooling methods.

Such transportation containers are extensively used in the professional transportation of blood. A weakness in existing transport systems is however, in the un- and reloading of blood products, as they are passed over to the reciever in containers with only short term isolation properties. The adherence to the cool chain is, in such cases, mostly not quantifyable and the period in which the required temperatures are maintained is very short.

A further problem is with the internal transport in clinics. Blood products that, for example, leave storage in preperation for the operation theatre, are not kept under temperature control as they are presently transported in simple insulated containers. If this blood product is then not used, it is not quantifyable whether the permitted temperature levels have been exeeded. In order to save and re-store this blood a complicated and extensive analytical test must be undertaken. Furthermore, most containers used to transport blood do not have any protective mechanism against tampering.

In order to create a cool chain, previous methods used to transport temperature sensitive products at the required temperature levels have been to use insulated chambers (i.e. boxes) that has an insulated inner layer together with a simple cooling device that is filled with a liquid of high specific enthalpy. A disadvantage in using this method is however, that the liquid with high specific enthalpy comes into direct contact with the packaging in which the blood is kept and adherence to the required temperature levels is not visible from the outside. Furthermore, the thermal enthalpy of the fluid is not effective enough.

In U.S. Pat. No. 5,235,819 an apparatus for storing and distributing materials is described.. The apparatus maintains products at an intended temperature during transporation and storage at an ambient temperature deviating from the intended temperature. The invention features a container that holds the products and whose walls render heat transfer difficult.

The container includes a main container body with a bottom and a side section that together define one or more integrated compartments suitable for storing a solidifiable substance.

The invention does not consist of modular identical halves or frame structures that may be stacked on top of each other to create a flexible, modular system enabling variable inner volumes to suit different product sizes, thus maximising the inner volume for the amount of product being stored whilst also being completely surrounded by the temperature-regulating fluid. The fact that this transport apparatus is not modular makes it impossible to transport variable volumes of products such as medications, blood and organs which are the intended products to be transported in this present invention.

An insulated modular cooler comprising in one embodiment a plurality of tubular housing sections and a plurality of tubular hollow-walled insert housing containing a refrigerant in the hollow walls of the insert housings was invented by Basso (U.S. Pat. No. 4,517,815). The tubular housing sections can be secured end to end to form an elongated tubular housing. However, the tubular system has to incorporate an end cap to secure the product being transported inside, which functions like a thermal bridge so that heat from the outside can be easily conducted into the inner compartment of the tubular housing. There is no cooling fluid within this end cap which means that the cooling fluid does not surround the entire inner compartment. Furthermore, another bottom cap is required to close the system. The temperature stability of the product to be transported is therefore unpredictable because the cooling fluid does not surround the inner compartment completely. The invention does not consist of modular identical halves that may be stacked on top of each other and which require neither an end or bottom cap as is the case in this present invention, whereby the product being transported is totally surrounded by temperature regulating fluid.

A combination dental material mixing slab holder and cooler which includes a base plate having a pair of spaced, upwardly projecting ribs and a central well was invented by Drake (U.S. Pat. No. 3,858,410). This patent teaches that the heat sink means it is a stable liquid or solid material, having a relatively high latent or heat capacity. However, no modular dispositions are explained and the cooling liquid or solid material does not surround the inner compartment completely. The temperature profile through the cross sections is inhomogeneous due to the different conductivity of the lid and the container itself.

Various phase change formulations usable in thermal packaging systems using a single phase change material part in liquid and part in solid form to confine the temperature of the product within a predetermined range was described by Malach (U.S. Pat. No. 6,482,332).

The temperature ranges are determined by selection of the phase change material. Blends such as butandiol, selected amounts of distilled water and nucleating agents can be formulated to achieve phase changes from +40° to –30°C. However Malach does not describe a modular system or a double walled apparatus that surrounded the inner compartment completely by phase change material. Furthermore the construction of the described container requires an end cap and a bottom cap for closure.

Sheehan invented a portable cooler for use in transporting medicines including an insulative housing containing a coolant (U.S. Pat. No. 4,322,954). One compartment is made for a coolant and the other for the product. A heat tube connects both compartments. The device includes a carrying strap and latches. The device is not constructed like a modular expandable system and the cooling liquid or material does not directly or completely surround the product to be transported.

MacDonald teaches in patent (U.S. Pat. No. 5,058,397) a cryogenic storage container for biological specimens that include a cooling gel or medium to keep the specimens at a low temperature.
The storage box includes a rectangular housing having a chamber filled with a coolant gel, and a plurality of spaced, tube supporting wells opening at their upper ends. A cover, which is connected to the housing, contains a sealed envelope containing coolant gel. The device includes hinges and latches, but does not consist of a modular system that surrounds the inner volume completely.

Schea (U.S. Pat. No. 5,181,394) disclosed a shipping unit for containers of liquid compositions, such as solutions of biologically active proteins. A phase change material such as carboxymethylcellulose gel is disposed in the enclosed space between sidewalls and maintains the temperature of the inner containers. A freeze indicator provides an irreversible visual signal upon reaching a temperature intermediate the nucleation temperature of the liquid composition and the freezing temperature of the phase change material. Thus thermocouple devices of varying kinds and simple devices such as described in U.S Pat. Mo. 4,191,125 are quite suitable as the freeze indicators. However, the device of Schea cannot be used as a modular system to increase the inner volume and it is not constructed to surround an inner compartment by phase change material to avoid heat bridges.

Another further problem is that all of the described systems do not provide complete surrounding with the phase change material causing an unpredictable inner temperature alteration due to heat bridges. When the inner compartment of a container is surrounded

completely in a homogenous manner the inner temperature is fully controlled by the phase change allowing a maximum transport time to be achieved with predictable temperature values.

Since it would be obvious to one of ordinary skill in the art that complete surrounding of the inner compartment enhances the temperature stability of the inside product is it not obvious for one of ordinary skills to combine both features of modularity and the complete surrounding of phase change material and also construct this by avoiding a double walled system without an end cap or bottom cap.

The purpose of this invention is to provide a transport system for products at consistent and predictable temperatures, specifically blood and medical products, which hinders tampering of single or multiple units and maintains the permitted temperatures. A further purpose of this invention is to show on the container whether the permitted temperatures have been maintained.

The solution is found with a system to transport products at consistent temperatures, specifically the temperature regulated transport of blood and medical products with the properties according to claim 1. Andvantageous properties of the invention are described in fully in the claim.

SUMMARY OF THE INVENTION

In accordance with the invention the system, a storage, protection and transport container for easily perishable products, made from double walls that are filled with a fluid or solid latent temperature regulating fluid to give it insulating properties, enables the transport of products at consistent temperatures, especially to transport blood and medical products.

A major property of the invention is that the container, consisting of two identical halves (1) and (10) or frames (20) that close together; snap tightly shut due to a series of notches (11) and indentations (2) along the perimeter of each half or frame. When the two halves are closed together a protective space (3) is created within, which enables the storage of blood and/or pharmaceuticals. The construction of the identical halves allows the product being stored or transported to be completely surrounded by the temperature-regulating fluid. Furthermore, each identical half (1; 10) provides temperature-regulating properties and acts as a first end cap or bottom end cap.

The storing, protection and transporting system of the present invention comprises:

(1) Two double walled halves (1 and 10) with notches (11) and indentations (2) along the perimeter edges (5 and 6) that allow them to fit tightly together and create an inner space (3) for the storage and transport of blood, blood products (30) or pharmaceuticals.
(2) A double walled frame (20) with notches (11) and indentations (2) along the perimeter edges (4) that allow it to fit tightly together with the two other halves (1) to create a larger inner space for the storage of blood, blood products (30) or pharmaceuticals.
(3) A contained latent temperature regulating fluid (in each half and frame), specifically paraffin, or a carrier immobilised paraffin, or a saline solution, or an ethanol water mix or a buthandiol water mix which provide a plateau of constant temperatures of -20°C to -40°C, 2°C to 6°C and 20°C to 24°C.
(4) Eyelets (9) on each half (1) which allow the container to be sealed with a lead seal to stop undesired or at least recognisable opening of the container
(5) Indentations (14) on each half to allow for a carrying strap to be fitted.
(6) A sealed opening on each half (12) to allow them to be filled with the latent temperature regulating fluid.
(7) Each half is fitted inside with a thermometer (34), specifically a self-adhesive strip thermometer or a liquid crystal thermometer and/or an electronic readable temperature gauge.

DESCRIPTION OF THE DRAWINGS

Other properties, peculiarities and advantages of the invention are shown in diagrammatical form and described as follows:

Fig. 1: an innerview perspective of the storage, protection and transport container according to the invention.

Fig. 2: an outer view perspective of the part shown in Fig. 1 of the storage, protection and transport container according to the invention.

Fig. 3: a perspective view of the frame that fits together with the parts in Fig.1 and Fig.2 of the storage, protection and transport container according to the invention.

Fig. 4: a perspective outer view of the storage, protection and transport container that consists of the parts of Fig. 1, Fig.2 and Fig. 3 according to the invention.

Fig.5: a perspective view of a single half (1) combined with frames (20) that fit together and form a storage, protection and transport container according to the invention.

Fig 6: two schematic cross sections of two identical halves (1) containing one or two blood product units (30) depending on the addition of a double walled frame (20) to extend the inner volume according to the invention.

Fig. 1: The system to transport products at consistent temperatures consists of two identical halves, shown in Figure 1 and Figure 2. Fig. 1 shows an innerview perspective of one half. This half (1) can be locked together with a second same half (10) by means of notches (11) and indentations (2). The first half locked together with a second half creates an inner space (3), which is completely shielded from the outside elements due to the double walls of the two halves (1 and 10) and the tongues (4) and grooves (5) along the connecting edges (6) of the container. This space (3) allows for the storage of blood products (shown in Fig. 6) or other products such as antibodies, cells or pharmaceuticals in their original packaging.

Fig. 2: The outer view perspective of one half is shown in Fig. 2. The halves (1 and 10) contain a liquid or solid temperature-regulating medium within the double walls and have sealable openings (12) to fill them. The parts have indentations (14) on the outside to fit a carrying strap and protrusions (7) and indentations (8) to enable them to lock snugly together and allow for stacking. With the aid of a sealing tie (not shown) both parts can be sealed together.

Fig. 3: Respective characteristics are marked in Fig.1 and 2. A double walled frame (part 20) fits together with parts 1 and 10 by means of notches (11) and indentations (2) along the connecting edges (6) thus increasing the interior volume.

Fig. 4: Respective parts are marked in Fig.1, 2 and 3. The system used to transport products at consistent temperatures with improved protection and storage is achieved by fitting a half (1) together with a second same half (10) and a frame (20) which fits between both halves by means of notches (11) and indentations (2). The identical halves (1 and 10) are featured with an eyelet (9) on both sides that allows sealing of the whole container.

Fig. 5: Respective parts are marked in Fig.1, 2 and 3. The inner volume (3) can be increased by stacking a single or chosen multiples of frames (20) to create a modular system, whereby the user can self determine the inner volume (3) that is required to store or transport the product. Two identical halves (1) not only provide temperature insulation for the product(s) but also create a bottom end and top end cap that closes the container, whilst also totally encompassing the product homogenously with temperature regulating fluid. The frames and halves lock tightly together by means of notches (11) and indentations (2).

Fig 6: Respective parts are marked in Fig.1, 2 and 3. The system to transport products at consistent temperatures is shown in a schematic cross section. The two identical halves can be equipped with an carrying strap (32) or an liquid crystal thermometer (34)and form an inner volume (3) that can be used to store one or more blood products (30). The inner volume of the structure can be expanded by attaching frames (20). Moreover, by choosing the number of frames used (20) not only is the inner volume thus determined but also the total amount of phase change material (the more frames used, the greater the volume of phase change material and thus also the length of transportation time (the greater the volume of phase change material, the longer the transportation time).

The double wall of parts (1; 10; 20) all have sealable openings (12) which enable filling or emptying with a latent temperature regulating fluid, specifically paraffin or a carrier immobilised paraffin or a buthandiol water mix, a watery salt mix or an ethanol water mix, which has a melting point of either 20 to 24° C, 2 to 6° C, –20 to -30° C and –20 to -40° C. Alternatively, n-paraffins with the formula C_nH_{2n+2} can be used to stabilise temperatures above 0° C.

The transparent walls of the storage, protection and transport container (1; 10; 20) enables one to see the condition of the temperature regulating fluid and that the required temperatures have been adhered to. In this way blood products such as erythrocyte concentrates and thrombocytes can easily be transported and handled at temperatures of 2 to 6° C and 20 to 24° C.

The container, made up of two (Fig. 6) or the three (Fig. 4) double walled parts which fit together to create an inner space for the products (30) in which the temperature should remain constant, is fitted with a thermometer (34), specifically a self adhesive strip thermometer, a liquid crystal thermometer and/or an electronic readable temperature gauge which can be set to read -temperatures of 20 to 24° C, 2 to 6° C, -20 to - 30° and -20 °C to -40 °C.

The container, made up of two or three complimentary double walled parts each have at least one eyelet (9) which allows the halves to be sealed together with a led seal, to prevent or show any undesired opening of it as shown in Fig. 4.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with the invention the system, a storage, protection and transport container for easily perishable products, made from double walls that are filled with a fluid or solid latent temperature regulating fluid to give it insulating properties, enables the transport of products at consistent temperatures, especially to transport blood and medical products.

A major property of the invention is that both identical halves (Fig 1 and 2) that fit together are double walled, which together with a similarly produced frame (Fig 3) that also snaps with its notches (11) onto the indentations (2), increases the protective storage space (3) between them. In this way, the one half serves as the top (10) and the other as the bottom (1) of the container (Fig. 4 and Fig. 6), thus the system does not require an extra lid and the product being stored or transported within the system is completely surrounded by the temperature regulating fluid that is held between the double walls. The double walled frame (20) is also filled with a liquid, which according to the energy applied to it, may be charged with or emmit a required temperature. These double walled halves and frames filled with the temperature regulating fluid can be fitted together in such a way, so that a modular system is created, whilst the inner volume can also be varied depending on the number of frames used (Fig 5 and Fig. 6), providing an inner volume space (3) of between 250ml and 100 litres.

Another major property of the invention is that the container, consisting of two identical halves that close together, snap tightly shut due to a series of notches (11) and indentations (2) along the perimeter of each half (Fig 1, 2 and 3). When the two halves are closed together a protective space (3) is created within, which enables the storage of blood and/or medical products.

Another property of the invention is that the double wall of each part is filled with a latent temperature regulating fluid which has a melting point of 2 to 6° C, specifically paraffin or a carrier immobilised parafin, which maintains the temperature of the storage space within at a consistent temperature of 2 to 6° C. The container is therefore capable of storing and

transporting erythrocite concentrates and other blood products, antibodies, cells or biotechnically produced pharmaceuticalls which have to be transported at 2 to 6° C.

Another property of the invention is that n-hydrocarbons, namely n-paraffins with the formula C_nH_{2n+2} can be used to stabalise temperatures above 0 °C.

Another property of the invention is that the container is filled with a saline solution or an ethanol water mix that has a consistency between fluid and solid between the temperatures of -20 °C and -40 °C.

Another property of the invention is that the double wall of the container is filled with a latent temperature regulation fluid which has a melting point of 20 to 24° C, specifically paraffin Or a carrier immobilised paraffin or a buthanol water mix in order to keep the inner storage space at a constant temperature of 20 to 24° C. The container is therefore capable of storing and transporting thrombocytes and other blood products that have to be transported at these temperatures.

Another property of the invention is that the material from which the double walled container is produced is transparent, specifically a transparent plastic, so that the condition of the temperature regulating fluid within is visible. It is therefore easy to check the temperature levels making the container useful for cool chain transportation.

Another property of the invention is that the double walled half is produced from impervious plastics such as polyamid e.g. kevlar, or from metals such as aluminium, steel or iron.

Another property of the invention is that the containers may be stacked as there are protrusions (7) and indentations (8) on the back of the container allowing for this as shown in Fig. 2.

Another property of the invention is that there are two closures attached to the transport container that are sealable.

Another property of the invention is that the container is fitted with at least one eyelet (9) which can be sealed so that undesired opening can be avoided or is at least recognisable as indicated in Fig. 4.

Another property of the invention is that the parts of the storage, protection and transport container are fitted with tongue and groove (4 and 5) to avoid temperature loss as shown in Fig. 1.

Another property of the invention is that the parts of the storage, protection and transport container are connected by a hinge.

Another property of the invention is that the container may be fitted with a carrying strap.

Another property of the invention is that the container is fitted inside with a thermometer (34), specifically a self sealing strip thermometer or a liquid crystal thermometer and/or an electronic readable temperature gauge as schematically indicated in Fig. 6.